K033675

JAN 15 2004

510(k) Summary
for
Sirona Dental Systems
ProSmile Air Polisher and Prophylaxis Powder

1. SPONSOR

Sirona Dental Systems GmbH
Farbrikstrasse 31
64625 Bensheim
Germany

Contact Person: Fritz Kolle
Regulatory Manager

Date Prepared: November 21, 2003

2. Device Name

Proprietary Name:	ProSmile Air Polisher and Prophylaxis Powder
Common/Usual Name:	Air Polisher, Abrasive Polishing Agent
Classification Name:	Air Brush

3. Predicate Devices

EMS Air Flow Handy 2 Air Polisher and Powder, K022119

4. INTENDED USE

The ProSmile Air Polisher is intended for removing deposits, plaque, and staining on all visible tooth surfaces as well as in fissures and interdental areas. The ProSmile is also intended for the following prophylactic applications:

- cleaning teeth prior to scaling
- cleaning teeth prior to fluoridation
- cleaning teeth prior to bleaching
- cleaning teeth prior to using bonding materials

5. DEVICE DESCRIPTION

The ProSmile consists of the handpiece, ProSmile Prophylaxis Powder, the powder jet nozzle, test card, and hose coupling. The components that are integral to the C8+ Dental Operative Unit and used during ProSmile operation are the powder chamber, powder chamber venting button, water regulator, air/powder regulator, and foot control. The ProSmile is a pneumatically operated device that is offered with two powder jet nozzles.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

Both the ProSmile and EMS Air Flow Handy 2 devices are polishers intended for removing plaque deposits and stains using a mixture of water, air, and powder in dental cleaning procedures. The overall design of the proposed device is similar to that of the predicate device. Both include a dental handpiece and powder accessory, controls for delivery of the air/water/powder mixture, and delivery nozzles. Both devices allow for control of the /powder/air from the foot control. The proposed device differs from the predicate device in that the powder container for the ProSmile is located in the C8+ dentist's element, while the powder container for the predicate device is located in the device handpiece.

7. PERFORMANCE TESTING

The appropriate design verification and design validation activities were conducted to address the potential risks identified in the Hazard Analysis. These activities included electrical safety testing, electromagnetic compatibility testing, and functional testing. The results confirmed that the ProSmile is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 15 2004

Sirona Dental Systems GmbH
C/O Ms. Mary McNamara-Cullinane, RAC
Staff Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K033675
Trade/Device Name: Prosmile Air Polisher and Prophylaxis Powder
Regulation Number: 21 CFR 872.6080
Regulation Name: Airbrush
Regulatory Class: II
Product Code: KOJ
Dated: November 21, 2003
Received: November 24, 2003

Dear Ms. McNamara-Cullinane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033675

Device Name: ProSmile Air Polisher and Prophylaxis Powder

Indications for Use:

The ProSmile Air Polisher is intended for removing deposits, plaque, and staining on all visible tooth surfaces as well as in fissures and interdental areas. The ProSmile is also intended for the following prophylactic applications:

- cleaning teeth prior to sealing
- cleaning teeth prior to fluoridation
- cleaning teeth prior to bleaching
- cleaning teeth prior to using bonding materials

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K033675

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)